

# **7. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**OCT 16 2002**

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

**510(k) Number:** K022805

**Date of Summary Preparation:**  
August 6, 2002

**Submitter:** Applied Biotech, Inc.  
**Contact Person:** Vivianne Noetzel  
**Phone:** 858-756-8483  
**FAX:** 858-759-7492  
**Address:** P.O. Box 9433  
17394 Via Del Bravo  
Rancho Santa Fe, California 92067

**Manufacturing Site:** Applied Biotech, Inc.  
10237 Flanders Court  
San Diego, California 92121

**Phone:** 858-587-6771

**Establishment Number:** 2028231

**Device Trade Name:** DrugFree@Home™: Cocaine Test

**Device Common Name:** Cocaine and cocaine metabolite testing system

**Device Classification:** Class II (21 CFR 862.3250)

**Device Product Code:** DIO

**Performance Standards:** None established (as a medical device) under Section 514.

**Device Description:** One step immunoassay for the detection of cocaine in urine.

**Intended Use** The DrugFree@Home™: Cocaine Test is an *in vitro* diagnostic screen for the detection of cocaine in urine. The DrugFree@Home™: Cocaine Test has a cutoff concentration of 300ng/mL. The DrugFree@Home™: Cocaine Test is used to obtain a visual, qualitative result and is intended for over-the counter sale to laypersons.

**Indication for Use** The DrugFree@Home™: Cocaine Test is an *in vitro* diagnostic screen test for the rapid detection of cocaine and its metabolite, benzoylecgonine in human urine at above a concentration of 300ng/mL. The test provides a preliminary analytical result, and if necessary, a pre-paid confirmation test (GC/MS) is included. The DrugFree@Home™: Cocaine Test is used to obtain a visual, qualitative result and is intended for over-the counter sale to laypersons.

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**Substantial Equivalence Claim to:**

DrugFree@Home THC/COC (07/03/2001 K002253).

**Technology:**

The DrugFree@Home™: Cocaine Test uses a one-step sandwich immunoassay technology based on the immunochemical principal of recognition and formation of specific antibody/target drug/antibody/complexes.

**Performance:**

The DrugFree@Home™: Cocaine Test for home use was evaluated in a consumer accuracy study by comparing consumer test results against GC/MS reported values. The study resulted in 98.3% agreement between the consumer test results and the GC/MS reported values

**Conclusion:**

For the reasons mentioned above, it may be concluded that the DrugFree@Home™: Cocaine Test is substantially equivalent to commercially available OTC devices for home use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 16 2002

Applied Biotech, Inc.  
c/o Ms. Vivianne Noetzel  
Noetzel Terratech  
P.O. Box 9433  
Rancho Santa Fe, CA 92067

Re: k022805  
Trade/Device Name: DrugFree@Home™ Cocaine Test  
Regulation Number: 21 CFR 862.3250  
Regulation Name: Cocaine and cocaine metabolite test system  
Regulatory Class: Class II  
Product Code: DIO  
Dated: August 6, 2002  
Received: August 23, 2002

Dear Ms. Noetzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

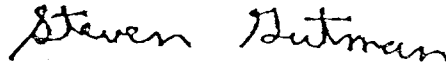
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

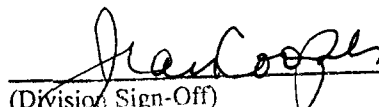
Enclosure

**6. INDICATIONS FOR USE STATEMENT****510(k) Number:**K02 2805**Device Name:**

DrugFree@Home™: Cocaine Test

**Indication for Use**

The DrugFree@Home™: Cocaine Test is an *in vitro* diagnostic screen test for the rapid detection of cocaine and its metabolite, benzoylecgonine in human urine at above a concentration of 300ng/mL. The test provides a preliminary analytical result, and if necessary, a pre-paid confirmation test (GC/MS) is included. The DrugFree@Home™: Cocaine Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K022805

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use X